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AUG 3 1 2007

G SPECIAL 510(k) SUMMARY

For the modification to Bioretec ActivaPin™ (K061164)

MANUFACTURER

Bioretec Ltd.
Hermiankatu 22, Modulight Building
FI-33720 Tampere
FINLAND

Contact person:
Ms. Mari Ruotsalainen
Quality Manager
Phone: +358 20 778 9514
Fax: +358 3 317 0225
Mari.Ruotsalainen@bioretec.com

Date prepared: June 28th, 2007

DEVICE NAME

Trade Names: Bioretec ActivaPin™, NexFix™ RFS Pin (Resorbable Fixation System)

Common Name: Pin, Fixation

ESTABLISHMENT REGISTRATION NUMBER

Bioretec Ltd. has been submitted the Establishment Registration form and is waiting for an Establishment Registration Number.

DEVICE CLASSIFICATION AND PRODUCT CODE

Device Classification Name: Pin, Fixation, Smooth

Classification Panel: Orthopedic

Regulation Number: 21 CFR 888.3040

Product Code: HTY

PREDICATE DEVICES

Bioretec ActivaPin™ (K061164)

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DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The modified **ActivaPin™** is identical to the currently cleared device except for the modification. The only modification to the initial 510(k) K061164 to be cleared is adding a Disposable Pin Applicator with K-wire for installation of ActivaPin™ and revising labeling accordingly. The change does not affect the intended use or alter the fundamental scientific technology of the device.

The **ActivaPin™** is indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization. Pins are available in several different dimensions, including diameters of 1.5 – 3.2 mm and lengths of 20 – 70 mm.

ActivaPin™ is made of completely bioabsorbable poly(L-lactide-co-glycolide) (PLGA), and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body. As the operated bone fracture or osteotomy gains strength during healing, the **ActivaPin™** gradually loses its strength, however, maintaining its function at least 8 weeks. Bioabsorption takes place within two years thus eliminating the need for implant removal surgery.

EQUIVALENCE TO MARKETED PRODUCTS

The ActivaPin™ Bioabsorbable Pin and its instrumentation is substantially equivalent to the ActivaPin™ cited as predicate device above.

The Bioretec ActivaPin™ with its modified instrumentation has the same intended use, principles of operation and technological characteristic as the predicate device. Adding a Disposable Pin Applicator with K-wire for installation of ActivaPin™ and revising labeling accordingly does not raise any questions of safety and effectiveness.

Microbiological testing determined that the ActivaPin™ and the ActivaPin™ Disposable Pin Applicator with K-wire instrument set has substantially similar performance as compared to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2007

Bioretec Ltd.
% Ms. Mari Ruotsalainen
Quality Manager
Hermiankatu 22, Modulight Building
FI-33720 Tampere
FINLAND

Re: K071863

Trade/Device Name: Bioretec ActivaPin™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: August 1, 2007
Received: August 3, 2007

Dear Ms. Ruotsalainen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

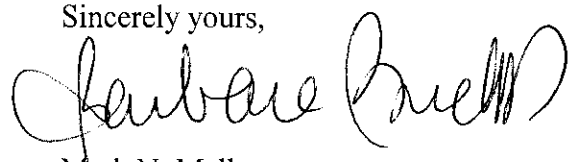
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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F Indications for Use Statement

Submitter: Bioretec Ltd.

510(k) Number: K071863

Device Name: ActivaPin™

Indications for Use:

The **ActivaPin™** is indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

Contraindications:

1. Fractures and osteotomies of diaphyseal bone.
2. Fractures and osteotomies in weight bearing cancellous bone.
3. Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient cooperation cannot be guaranteed.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071863